Q. Code:958784

Reg. No. | | | | | | | | | | | | | |

B.E. / B.TECH. DEGREE EXAMINATIONS, MAY 2024

Sixth Semester

BT18002 – BIOPHARMACEUTICAL TECHNOLOGY

(Biotechnology)

(Regulation 2018/2018A)

TIME:3 HOURS **MAX. MARKS: 100**

COURSE OUTCOMES	STATEMENT	RBT LEVEL
CO 1	Recognize the legal steps involved in progressing a new drug to market and to grab the current regulatory acts and safety norms of the modern pharmaceutical industries.	**2**
CO 2	Illustrate the mechanism of drug action and pharmacokinetics of a given drug.	**2**
CO 3	Identify the requirements to set up a biopharmaceutical industry and the applications of unit operations in biopharmaceutical industry.	**2**
CO 4	Evaluate different pharmaceutical parameters for the current and future biotechnology related products on the market.	**3**
CO 5	Investigate the novel pharmaceutical products, current medicines and their applications in therapeutic and diagnostic fields.	**3**

PART- A(10x2=20Marks)

(Answer all Questions)

		CO	RBT LEVEL
1.	Define Pharmacoeconomics.	**1**	**2**
2.	Provide examples of common drug targets in the human body.	**1**	**2**
3.	How is radioactivity used in determination of pharmacokinetics of a drug?	**2**	**2**
4.	State the significance of first pass effect in drug metabolism and bioavailability.	**2**	**2**
5.	What is synthetic reaction? Give an example.	**3**	**2**
6.	Explain the difference between an active pharmaceutical ingredient and an excipient.	**3**	**2**
7.	Sort-out the mechanical properties of the plastic packaging materials.	**4**	**3**
8.	What are the analytical methods and tests used to assess the quality of different drugs and pharmaceutical products?	**4**	**3**
9.	Are antibiotics a suitable treatment for the common cold? Justify.	**5**	**3**
10.	Give the meaning of the following: vasectomy & expectorant.	**5**	**3**

PART- B (5x 14=70Marks)

			Marks	CO	RBT LEVEL
11. (a)		Discuss the stages of drug development from discovery to market approval. Include the identification of drug targets, lead compound discovery, preclinical testing, clinical trials, and regulatory approval processes.	**(14)**	**1**	**2**
		(OR)			
(b)	**(i)**	Describe the process of obtaining a patent for a pharmaceutical product, including the requirements for patentability, the application process, and the role of patent examiners and patent attorneys.	**(7)**	**1**	**2**

	(ii) Explore the ethical and regulatory considerations in therapeutic agent development and access.	**(7)**	**1**	**2**
12. (a)	Describe the factors that influence drug absorption kinetics. Discuss the physicochemical properties of drugs, such as solubility, lipophilicity, molecular size, and ionization, and how these properties affect drug absorption rates and bioavailability?	**(14)**	**2**	**2**
	(OR)			
(b)	Discuss the processes involved in drug metabolism, and their impact on drug clearance, bioavailability, and therapeutic efficacy.	**(14)**	**2**	**2**
13. (a)	Discuss in detail about the key chemical conversion processes employed in the pharmaceutical industry, and how do they contribute to drug synthesis and production?	**(14)**	**3**	**2**
	(OR)			
(b)	Discuss how laboratory-scale processes are translated into industrial-scale production, and how factors such as process optimization, equipment selection, and validation protocols ensure consistency, reproducibility, and scalability of biopharmaceutical manufacturing processes?	**(14)**	**3**	**2**
14. (a)	Compare and contrast wet and dry granulation techniques used in tablet manufacturing. Describe the principles, advantages, and disadvantages of each method, including the equipment involved, the process steps, and the characteristics of the resulting granules.	**(14)**	**4**	**3**
	(OR)			
(b)	Identify any two topical diseases where each of the four various types of ointment bases might be employed to deliver (an) active ingredient (s) and explain their formulation in detail.	**(14)**	**4**	**3**
15. (a)	Analyze the specific receptor interactions, signal transduction pathways, and neurotransmitter modulation involved in the analgesic effects of each drug class. Discuss how these mechanisms contribute to the efficacy, onset, duration, and potency of analgesic drugs.	**(14)**	**5**	**4**
	(OR)			
(b)	Explore emerging trends and advancements in laxative therapy, such as the development of novel formulations and targeted delivery systems, and their implications for improving patient outcomes in the management of constipation and related disorders.	**(14)**	**5**	**4**

PART- C (1x 10=10Marks)

(Q.No.16 is compulsory)

		Marks	CO	RBT LEVEL
16.	Discuss the potential applications of integrating artificial intelligence and machine learning algorithms into drug development processes to expedite the identification of novel drug targets and enhance the prediction of drug efficacy.	**(10)**	**5**	**5**

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